K120325 P1/2

JUL 18 2012

510(k) Summary for Watermark Medical Mobile Application

Submitter: Watermark Medical

Address: 1750 Clint Moore Road, Suite 101
Boca Raton, FL 33487

Corporate Contact: Frank Katarow, Chief Operating Officer
WaterMark Medical

Telephone: 877-710-6999

Establishment Registration #: 3008208119

Submission Contact: Michael J. Leigh, consultant
12715 Falcon Drive
Brookfield, Wisconsin 53005
Ph: (262) 957-6797

Trade Name: Connected Care Mobile Application

Predicate Device: Honeywell HomMed Genesis DM, K101242

Common Name: Patient Vital Signs Monitor

Classification Name:

Regulation Number	Product Code	Classification Name	Device Class
870.2910	DRG	Transmitters And Receivers, Physiological Signal, Radiofrequency	II
Medical device product codes also supported by Mobile Application by means of separate medical devices			
870.1130	DXN	Noninvasive Blood Pressure Measurement System	II
880.2700	FRI	Patient Weight Scale	I
870.2700	DQA	Oximeter	II
862.1345	NBW	Glucose Test System	II

Device Description:

The Connected Care Mobile Application is intended to receive, display and transmit patient information on a retrospective basis. The device is not intended for real-time monitoring or emergency use by patients or caregivers.

The mobile application is designed to operate on various platforms including tablet computers and smart phones, guiding a user through the vitals acquisition process via Bluetooth medical peripherals. Peripherals will include:

- Scale
- Glucose meter
- NiBP
- SPO2

Intended Use:

The Watermark Medical Mobile Application is intended for personal use. The Mobile Application collects vital signs data (including noninvasive blood pressure, pulse rate, weight and other data from optional add-on devices) then can transmit the data to a central database via a communication network. Use of the system allows retrospective review of certain physiological functions. The Mobile Application is intended for use with adult and pediatric patients over twelve years of age.

Performance Data:

The software validation results demonstrated that the Mobile Application was in compliance with the guidelines and standards referenced in the FDA reviewer's guides and that it performed within its specifications and functional requirements for software.

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of FDA regarding medical device software.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 18 2012

Watermark Medical, Inc.
c/o Mr. Michael J. Leigh
Consultant
12715 Falcon Drive
Brookfield, WI 53005

Re: K120325
Trade/Device Name: Connected Care Mobile Application
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitters and Receivers
Regulatory Class: Class II (two)
Product Codes: DRG, DXN, FRI, DQA, NBW
Dated: April 30, 2012
Received: June 27, 2012

Dear Mr. Leigh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): Kxxxx K120325

Device Name: Watermark Medical Connected Care Mobile Application

Indications For Use:

Mobile Application allows the user to collect vital signs data (including noninvasive blood pressure, pulse rate, weight and other data from optional add-on devices). The user can then transmit the data to a central database via a communication network. Use of the system allows retrospective review of certain physiological functions by qualified health care professionals. The Mobile Application is intended for use with adult and pediatric patients over twelve years of age.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K120325